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CONFIDENTIAL

**510(k) Summary of Safety and Effectiveness**  
**Influence, Inc.'s *StapleTac2 Bone Anchor System***  
**510(k) Number K000279**

This 510(k) notification is submitted by American Medical Systems, 10700 Bren Road West, Minnetonka, MN55343. The contact person is Sytlvia L. Gubbe, Compliance Programs Manager.

This 510(k) notification describes a device intended for soft tissue fixation to the pubic bone by means of bone anchors. It is indicated for vaginal sling procedures for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The *StapleTac2 Bone Anchor System* is substantially equivalent to Influence, Inc.'s *StapleTac Bone Anchor System* cleared under K992277 with respect to intended use, materials and performance of the bone anchors. The major difference between the two systems is that the anchor of the *StapleTac2 Bone Anchor System* uses two wings for fixation in the bone, while the predicate device uses four-wing anchors.

Information on risk analysis of the modifications and performance testing provided in the application demonstrates equivalence to the predicate device with respect to performance.

Based on the performance data gathered, the device modifications do not raise any new questions of safety or effectiveness.

Based on the information provided the *StapleTac2 Bone Anchor System* is substantially equivalent to the *StapleTac Bone Anchor System* with respect to intended use, technological characteristics, and performance.



**MAR - 1 2000**

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Sylvia Gubbe  
American Medical Systems  
10700 Bren Road West  
Minnetonka, MN 55343

Re: K000279  
Trade Name: StapleTac2 Bone Anchor System  
Regulatory Class: II  
Product Code: MBI  
Dated: January 28, 2000  
Received: January 31, 2000

Dear Ms. Gubbe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

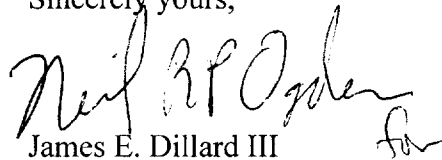
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations. \*

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Neil R. Dillard III", with a small flourish at the end.

James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE ENCLOSURE

510(k) Number  
(if known):

K000279

Device Name:

*StapleTac2* Bone Anchor System.

Indications for  
Use:

The *StapleTac2* Bone Anchor System is intended for soft tissue fixation to the pubic bone by means of bone anchors. It is indicated for vaginal sling procedures for the treatment of stress type (female) urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER  
PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)  
(Division Sign-off)

Division of General and Restorative Devices

*MSO for JED*

510(k) Number

K000279

Prescription Use *i*  
(Per 21 CFR 801.109)

OR

Over the Counter  
Use \_\_\_\_\_